

# THE FLORIDA BOARD OF PHARMACY

## ANNUAL REGULATORY PLAN 2015-16

This Annual Regulatory Plan is being filed and published pursuant to section 120.74, *Florida Statutes* (2015). The Plan covers the period beginning October 1, 2015 and ending September 30, 2016.

### PART ONE LAWS ENACTED OR AMENDED

Part One of the Plan addresses each law enacted or amended during the 2015 Legislative Session which creates or modifies the duties or authority of the Board of Pharmacy and Part One also address the mandatory rulemaking necessary to implement the law or laws enacted or amended. §120.74(1)(a), Fla. Stat. (2015).

#### A. Laws Enacted or Amended

BILL NUMBER	LAWS OF FLORIDA	FLORIDA STATUTE	DESCRIPTION OF AMENDMENT
Fla. CS for HB 279 (2015) Pharmacy	Act effective July 1, 2015, Ch. 2015-108, §1, Laws of Fla. (amending § 465.189, Fla. Stat. (2014))	§465.189, Fla. Stat. – Administration of Vaccines and Epinephrine Autoinjection	<ul style="list-style-type: none"> <li>• Authorizes Registered Pharmacy Intern to administer specified vaccines under the supervision of a pharmacist</li> <li>• Requires Registered Pharmacy Intern to be certified to administer vaccines</li> <li>• Requires Registered Pharmacy Intern to complete course work to become certified</li> </ul>

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**B. Rulemaking To Implement Law**

Rulemaking is necessary and mandatory to implement the newly enacted amendment to §465.189, *Florida Statutes*. To implement the legislative policy, the Board must engage rulemaking to adopt an application form for Registered Pharmacy Interns to utilize who wish to be certified to administer vaccines. §§120.54(1) and (16), Fla. Stat. (2015). The Board must also engage in mandatory rulemaking to approve the 20 hours of continuing education classes that the Registered Pharmacy Intern must take to be certified to administer vaccines. §465.189(6), Fla. Stat. (2015).

RULE NUMBER	RULE TITLE	NOTICE OF RULE DEVELOPMENT	NOTICE OF PROPOSED RULE
64B16-26.1031, Fla. Admin. Code.	Vaccine Certification Program	The Notice of Rule Development was published on May 6, 2015, in Volume 41, Number 88 of the <i>Florida Administrative Register</i> .	The anticipated date of publication of the Notice of Proposed Rulemaking is September 23, 2015.
64B16-26.1032, Fla. Admin. Code.	Immunization Administration Certification Application and Information	The Notice of Rule Development was published on July 23, 2015 in Volume 41, Number 142 of the <i>Florida Administrative Register</i> .	The anticipated date of publication of the Notice of Proposed Rulemaking is September 23, 2015.

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**PART TWO**  
**LAWS TO BE IMPLEMENTED THROUGH RULEMAKING**

Part Two of this plan address those laws which the Board of Pharmacy intends to implement through rulemaking by July 1, 2016 that are otherwise not covered pursuant to Part One of this Plan. This Part does not include emergency rulemaking or any other rulemaking that may become necessary that was not evident to the Board at the time of the submission of this plan. Additionally, the listing of a law to be implemented does not mean the rule will necessarily be adopted or effective by July 1, 2016. Rather, the Notice of Proposed Rulemaking is intended to be published In the *Florida Administrative Register* by July 1, 2016. §120.74(1)(b), Fla. Stat. (2015).

<b>Rule Number</b>	<b>Rule Title</b>	<b>Law Implemented</b>	<b>Intent of Rulemaking</b>	<b>Description of Changes To Be Made In Rulemaking</b>
64B16-26.351, Fla. Admin. Code.	Standards for Approval of Registered Pharmacy Technician Training Programs	§465.014, Fla. Stat. (2015).	Clarify; Update; Reduce Regulatory Costs	Comprehensive review and update approved programs by acceptance of more recognized accreditation bodies.
64B16-27.1001, Fla. Admin. Code.	Practice of Pharmacy	§§465.003; 014; 026, Fla. Stat. (2015).	Clarify	Comprehensive Review to determine if there is a need to update or amend the rule based on comments received from the Joint Administrative Procedures Committee.

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Rule Number	Rule Title	Law Implemented	Intent of Rule Making	Description of Changes to be Made in Rulemaking.
64B16-27.104(5), Fla. Admin. Code	Conduct Governing Pharmacists and Pharmacy Permittees	§465.018, Fla. Stat. (2015); §465.022, Fla. Stat. (2015)	Clarify, Update, Increase Efficiency, Decrease Discipline, Increase Safety of the Pharmacy Operation and Security of Controlled Substances	Review to update the responsibilities of the assigned Prescription Department Manager
64B16-27.831, Fla. Admin. Code.	Standards of Practice for the Dispensing of Controlled Substances for the Treatment of Pain.	§§ 465.003(6); 0155, 016, Fla. Stat. (2015).	Clarify, Increase Dispensing Efficiency and Accuracy; Educate; Improve Coordination with Prescribing Practitioners	A comprehensive review is under way to determine the best way to help increase verification accuracy of prescriptions to prevent diversion and to ensure those prescription based on a legitimate medical need are being dispensed
64B16-28.100, Fla. Admin. Code.	Pharmacy Permits – Applications and Permitting	Chapter 465, Fla. Stat. (2015).	Increase Efficiency and Simplify	Update all applications
64B16-28.1081, Fla. Admin. Code	Regulation of Daily Operation Hours	§465.022, Fla. Stat. (2015).	Clarify, Increase Efficiency; Reduce Regulation	To clarify how many hours a pharmacy must remain open and the types of notices are required to inform the public
64B16-28.2021, Fla. Admin. Code.	Change of Ownership	§§ 465.003, 018, 019, 0193, and 022, Fla. Stat. (2015)	Clarify	To review and clarify what the definition of a change of ownership should be in light of other relevant statutory requirements for owning a pharmacy
64B16-28.450, Fla. Admin. Code.	Centralized Prescription Filling, Delivering, and Returning	§§ 003; 019; 022, and 0265, Fla. Stat. (2015).	Simplify, Clarify, Increase Efficiency, Reduce Regulatory Burden	Review current requirements to determine the necessity of a hard copy versus electronic document

Rule Number	Rule Title	Law Implemented	Intent of Rule Making	Description of Changes to be Made in Rulemaking
64B16-28.702 (6)(b)4, Fla. Admin Code.	Modified Class II Pharmacies	§465.019(2)(c) and §465.022, Fla. Stat. (2015).	Increase efficiency and Reduce Regulatory Burden	To clarify and simplify the perpetual inventory
64B16-29.001, Fla. Admin. Code.	Definition	§828.055, Fla. Stat. (2015).	Clarification	Review for necessary updates and clarification
64B16-30.001, Fla. Admin. Code.	Disciplinary Guidelines	§456.079, Fla. Stat. (2015).	Increase Efficiency and Clarification	To make certain and clarify that each statutory violation has a corresponding disciplinary guideline
<b>COMPOUNDING RELATED RULES</b>				
64B16-27.700, Fla. Admin. Code.	Definition of Compounding	§466.003 and §465.0155, Fla. Stat. (2015).	To ensure the rule does not conflict with state or federal regulation and to clarify compounding for animal use	To address concerns raised by the Joint Administrative Procedures Committee and eliminate any potential conflict with federal law
64B16-27.797, Fla. Admin. Code.	The Standards of Practice for Compounding Sterile Products	§§465.0155; 022, Fla. Stat. (2015).	Clarification	The rule is designed to be updated as often as needed for the board to clarify any confusion regarding the adopted and incorporated standards related to sterile compounding

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**PART THREE**  
**UPDATES TO PRIOR YEAR'S PLAN**

Part Three of the Plan address whether there is any desired updates to the prior year's regulatory plan. §120.74(c), Fla. Stat. (2015). There are not any desired updates to the prior year's annual regulatory plan.

**PART FOUR**  
**CERTIFICATION PURSUANT TO §120.74(1)(d), Fla. Stat. (2015)**

The undersigned hereby certify that they have reviewed this Annual Regulatory Plan and that the Board of Pharmacy regularly reviews all of its rules to determine if the rules remain consistent with the Board's rulemaking authority and the laws being implemented, with the most comprehensive enhanced review having been completed on the 30th day of June, 2015.

**/S/ MW**

Electronic Signature  
Michele Weizer, Doctor of Pharmacy  
Chair of the Board of Pharmacy

**September 18, 2015**

Date Signed

**/S/ DDF**

Electronic Signature  
David D. Flynn, Esquire  
Assistant Attorney General  
Counsel to the Board of Pharmacy

**September 18, 2015**

Date Signed